II. REMARKS

Preliminary Remarks

Reconsideration and allowance of the present application based upon the foregoing amendment and following remarks are respectfully requested. Claims 1, 4-13, 15, 16, 23-26, 28-30, 32-36, and 39-61 are currently pending and at issue in the application.

Amended claim 1 is directed to an enteral formulation for nasogastric delivery comprising (a) an amino acid source, (b) a carbohydrate source, (c) a lipid source, and (d) a fatty acid delivery agent, being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid, the covalent bonding providing a protective effect to both the carrier and fatty acid from degradation in the stomach or small intestine, said carrier being any one of a starch, a non-starch polysaccharide, or oligosaccharide the fatty acid delivery agent being present in the formulation range of 0.25% w/v through to 5% w/v, and wherein the formulation can be delivered through an enteral feeding tube. Support for amended claim 1 may be found throughout the specification as originally filed, *e.g.*, on page 7, lines 14-19; page 19, line 30 to page 20, line 17; page 21, line 1 to page 22, line 25; and page 25, lines 6-16.

Amended claim 4 is directed to an enteral formulation for nasogastric delivery as in claim 1 wherein the formulation is capable of being stored for at least 24 hours and not forming a gel viscous solution or precipitate that is not easily resuspended. Support for amended claim 4 may be found throughout the specification, for example, on page 6, lines 6-16.

Amended claim 15 is directed to an enteral formulation for nasogastric delivery as in claim 1 wherein the carrier is a non-starch polysaccharide or oligosaccharide. Support for amended claim 15 may be found throughout the specification as originally filed, *e.g.*, originally filed claim 15 and page 24, lines 29-33.

Amended claims 7, 16 and 23 have minor changes. Claim 7 was amended to correct a minor typographical error regarding the word butyrate. Amended claim 16 is now directed to an enteral formulation for nasogastric delivery as in claim 15 wherein the non-starch polysaccharide is selected from the group consisting of inulin, chitin, β glucans, mucilages, agar, carageenans, and gums including guar, arabic, xanthan, tragacanth, locus bean and psyllium. Claim 23 is now dependent upon claim 6 instead of canceled claim 13.

Amended claim 39 is directed to a method of elevating the level of a fatty acid in the colon of a human or animal, including the step of delivering a fatty delivery agent in a physiologically acceptable medium through a feeding tube to elevate the level of the fatty acid, the fatty acid delivery agent being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid, the covalent bonding providing a protective effect to both the carrier and fatty acid from degradation in the stomach or small intestine, said carrier being a starch, a non-starch polysaccharide or an oligosaccharide, the fatty acid delivery agent being present in the formulation range of 0.25% w/v through the 5% w/v. Support for amended claim 39 can be found throughout the specification as originally filed, e.g., on on page 7, lines 14-19; page 19, line 30 to page 20, line 17; page 21, line 1 to page 22, line 25; and page 25, lines 6-16.

New claims 63 and 64 further define the formulations of claim 1. Support for new claims 63 and 64 can be found throughout the specification, and no new matter has been added.

New claims 65-78 ultimately depend and further define the method claim 39. Support for new claims 65-78 can be found throughout the specification, and no new matter has been added.

The applicants do not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserve the right to pursue such subject matter in continuing applications.

Patentability Remarks

Rejection Under 35 U.S.C. §103(a)

On pages 2-4 of the official action, the examiner rejected claims 1, 4-13, 15, 16, 23-26, 28-30, 32-36, and 39-61 under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,723,446 (hereinafter Gray *et al.*) in view of U.S. Patent No. 5,840,860 (Annison *et al.*). Specifically, the examiner alleged Gray *et al.* teach an enteral formulation comprising a carbohydrate source, a lipid source, a fatty acid source (such as omega-3 and omega-6), minerals, vitamins in a ready to use can. The examiner further asserted that although Gray *et al.* do not expressly teach that the carrier is a non-starch polysaccharide, Annison *et al.* teach a fatty acid delivery system comprised of a fatty acid source where the carbohydrate (i.e., starch) serves as the carrier. The examiner further alleged Annison *et al.* teach the bond

between the fatty acid and the carrier is preferably an ester bond and the degree of substitution is in the range of 0.05 to 2. The examiner concluded that one of ordinary skill in the art would be motivated to combine the teachings of the cited references with the expectation of enhancing the nutritional value of the formulation.

With regard to the secondary reference, and as a preliminary matter, the applicants respectfully submit that Annison *et al.* are not available for use as prior art in a rejection based upon 35 U.S.C. §103(a) in view of 35 U.S.C. §103(c). Specifically, the applicants note that at the time the presently claimed invention was made, it and the invention of Annison *et al.* were owned by the same assignee (Commonwealth Scientific and Industrial Research Organization).

In support of this position, applicants have enclosed a copy the "Assignment of Nonprovisional Application" (see Appendix A), which indicates that the presently claimed invention was assigned to the Commonwealth Scientific and Industrial Research Organization. U.S. Patent No. 5,840,860 (Annison *et al.*) indicates on the front page the rights of this invention have been assigned to the Commonwealth Scientific and Industrial Research Organization (see Appendix B). Therefore, in view of the foregoing and the fact that Annison *et al.* could only qualify as prior art under one or more subsections of (e), (f), and (g) of 35 U.S.C. §102, the applicants submit that the cited U.S. patent cannot qualify for use as prior art in a rejection based upon 35 U.S.C. §103(c).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references (or reference when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicants' disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

The examiner bears the burden of establishing a *prima facie* case of obviousness and "can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Fine*, 5 U.S.P.Q.2d 1598 (Fed. Cir. 1988). To support a conclusion that a claimed composition is obvious, either: (a) the references must expressly or impliedly suggest the claimed composition to one of ordinary

skill in the art, or (b) the examiner must present a convincing line of reasoning as to why a person of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q.972, 973 (Bd. Pat. App. & Inter. 1985).

Solely to expedite prosecution, and without prejudice to the applicants right to seek broader claims in a continuing application, the applicants have canceled claim 13 thereby obviating the rejection of this claim. With regard to the remaining pending claims, the applicants submit that Gray *et al.* neither teach nor suggest the applicants' claimed invention, *i.e.*, an enteral formulation for nasogastric delivery comprising (a) an amino acid source, (b) a carbohydrate source, (c) a lipid source, and (d) a fatty acid delivery agent, being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid, the covalent bonding providing a protective effect to both the carrier and fatty acid from degradation in the stomach or small intestine, said carrier being any one of a starch, a non-starch polysaccharide, or oligosaccharide the fatty acid delivery agent being present in the formulation range of 0.25% w/v through to 5% w/v, and wherein the formulation can be delivered through an enteral feeding tube.

More particularly, Gray *et al.* does not teach or suggest that a carrier molecule (*i.e.*, a non-starch polysaccharide) is complexed with a fatty acid molecule such as short chain fatty acids. Gray *et al.*'s reference to "soluble or insoluble fiber to provide anti-diarrhoeal characteristics" at column 4, lines 29-33 fails to quantify the amount of fiber or teach what form the fiber should be processed in order to reach the colon and be effective. If one of skill in the art were to interpret this passage in Gray *et al.*, the standard fiber preparations would be introduced in the digestive tract in limited quantities through an enteral (nasogastric) tube in comparison to the applicants' teachings. Further, Gray *et al.* fails to address the viscosity problems associated with fiber carriers of fatty acids in enteric tubes. In contrast, the applicants teach that a fatty acid delivery agent, instead of a fiber component, is superior because delivery of an adequate quantity of usual fiber components gives rise to viscosity problems via an enteral tube. In order to avoid clogging or viscosity problems, an enteral tube with the fiber/fatty acid preparations as taught in Grey *et al.* would require large volumes of diluent, which would have adverse physiological effects on the patient. Accordingly, given the viscosity constraints inherent in providing higher levels of fiber in formulations derived via enteral tubes, the applicants submit it would not have been obvious

to one of skill to use the claimed fatty acid delivery agents in place of the soluble/insoluble fiber and/or carob pod powder or tannin extract taught in Grey *et al.*

Furthermore, there is no teaching or suggestion in Grey *et al.* that delivery of fatty acids through a enteral (nasogastric) tube could be achieved by reducing the concentration of the fatty acid delivery agent to a level of 5% w/v, and yet provide beneficial effects as presented in Examples 4 and 5 and page 16, lines 11-29. Applicants examples provide the unexpected results that the claimed carriers linked covalently to complex fatty acids can replace normal fiber supplements in order to provide a colonic benefit of SCFA or other fatty acids (and thus alleviating nutritional deficiencies of the large bowel) via an enteral tube.

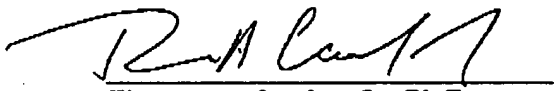
Accordingly, the applicants respectfully submit that one of skill in the art would not be directed to an enteral formulation for nasogastric delivery comprising (a) an amino acid source, (b) a carbohydrate source, (c) a lipid source, and (d) a fatty acid delivery agent, being a fatty acid covalently bonded to a carrier molecule by a bond hydrolysable in the colon to thereby release the fatty acid, the covalent bonding providing a protective effect to both the carrier and fatty acid from degradation in the stomach or small intestine, said carrier being any one of a starch, a non-starch polysaccharide, or oligosaccharide the fatty acid delivery agent being present in the formulation range of 0.25% w/v through to 5% w/v, and wherein the formulation can be delivered through an enteral feeding tube in view of Gray *et al.*

In summary, the applicants submit the primary reference, Gray *et al.*, neither teach nor suggest the applicants' claimed invention and the secondary reference, Annison *et al.*, is not a proper §103(a) reference due to 35 U.S.C. §103(c). Accordingly, without such teaching or suggestion, the examiner has not established a *prima facie* case of obviousness. Therefore, withdrawal of the rejection based upon 35 U.S.C. §103(a) is respectfully requested.

III. CONCLUSION

In view of the foregoing, the claims are now believed to be in form of allowance, and such action is hereby solicited. If any point remains at issue which the examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number below.

Respectfully submitted,
PILLSBURY WINTHROP LLP



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APPENDIX A

Please return signed/recorded to:

Pillsbury Winthrop LLP
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1600 Tysons Boulevard
McLean, VA 22102

USA Patent Appln.
Sole or Joint

For Inventions made outside USA
executed with or after application
Atty. Dkt. P | M# | Client Ref.

NONPROVISIONAL

ASSIGNMENT
OF NONPROVISIONAL APPLICATION

NONPROVISIONAL

In consideration of the sum of Ten Dollars ($10.00) and other good and valuable consideration paid to each of the undersigned, to wit:

INSERT NAME(S) OF INVENTOR(S)	(1) Anthony Richard BIRD	(2) Ian Ronald RECORD
	(3) David Lloyd TOPPING	(4)
	(5)	☐ x box if continued on page 2

the receipt and sufficiency of which are hereby acknowledged by the undersigned who at the request of, hereby sell(s), assign(s) and transfer(s) unto:

INSERT NAME(S) OF ASSIGNEE(S) & ADDRESS(ES): Commonwealth Scientific and Industrial Research Organisation
Limestone Avenue, Campbell, Australian Capital Territory 2612, Australia

(hereinafter designated "ASSIGNEE") the entire right, title and interest for the United States of America as defined in 35 U.S.C. 100, in the invention and all applications including any and all divisions, continuations, substitutes, and reissues thereof; and all resulting patents, known as

TITLE OF INVENTION: NASOGASTRIC ENTERAL FORMULATIONS

for which the undersigned executed an application for Letters Patents of the United States of America:

NOTE → → (Complete line A, B and/or C)
(A) ☐ even date herewith
(B) ☒ on 30 June 2000
(C) ☐ in U.S. Appln. No. / filed

AND the undersigned hereby authorize(s) and request(s) the United States Commissioner of Patents and Trademarks to issue said Letters Patent to the said ASSIGNEE, for its interest as ASSIGNEE, its successors, assigns and legals representatives; the undersigned agree(s) that the attorney of record in said application shall hereinafter act on behalf of said ASSIGNEE;

AND the undersigned hereby agree(s) to testify and execute any papers for ASSIGNEE, its successors, assigns and legal representatives, deemed essential by ASSIGNEE to ASSIGNEE'S full protection and title in and to the invention hereby transferred.

NOTE → → The undersigned hereby authorize(s) Pillsbury Winthrop LLP of the above address to insert hereon any further identification necessary or desirable for recordation of this document.

	INVENTORS	DATE SIGNED	WITNESSES
1): Name:	Anthony Richard BIRD	15/1/02	
2) Name:	Ian Ronald RECORD	24/1/02	
3) Name:	David Lloyd TOPPING	25/1/02	
4) Name:			
5) Name:			

APPENDIX B

US005840860A

United States Patent [19]

Annison et al.

[11] Patent Number: 5,840,860

[45] Date of Patent: Nov. 24, 1998

[54] FATTY ACID DELIVERY SYSTEM COMPRISING A HYDROLYZABLE BOND

[75] Inventors: Geoffrey Annison, The Concourse, Singapore; David L. Topping; Richard J. Illman, both of O'Halloran Hill, Australia

[73] Assignee: Commonwealth Scientific and Industrial Research Organization, Australia

[21] Appl. No.: 646,294

[22] PCT Filed: Nov. 17, 1994

[86] PCT No.: PCT/AU94/00713

§ 371 Date: Sep. 5, 1996

§ 102(e) Date: Sep. 5, 1996

[87] PCT Pub. No.: WO95/13801

PCT Pub. Date: May 26, 1995

[30] Foreign Application Priority Data

Nov. 17, 1993 [AU] Australia PM2454

[51] Int. Cl.[6] C07H 1/00

[52] U.S. Cl. 536/1.11; 525/50; 525/54.2; 514/54; 436/71

[58] Field of Search 554/35; 564/215; 525/54.2, 50, 54.21, 54.24, 54.31, 54.4; 436/71; 514/23, 54, 57, 58, 59, 60, 61, 62; 536/1.11, 2

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(List continued on next page.)

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[57] ABSTRACT

Delivery to the colon of fatty acids especially Short Chain Fatty Acids (SCFA) can be effected by covalently linking SCFA to a carrier that is preferably a form of carbohydrate, by an ester link. The SCFA is protected by its link with the carbohydrate through the small intestine, and where the carbohydrate is digestible in the small intestine such as a digestible starch, the starch can also be protected from digestion in the small intestine by the substitution. Levels of SCFA such as acetate, propionate and butyrate may be elevated to have beneficial effects in the prevention of colonic disorders such as rectal cancer, diverticulities, colitis, diarrhea and constipation.

118 Claims, 8 Drawing Sheets